UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JOHN J. BILLONE and
SANDRA BILLONE,

Plaintiffs,

v.

SULZER ORTHOPEDICS, INC.,

Defendant.

99-CV-6132
DECISION and ORDER

Plaintiffs John J. Billone and Sandra Billone (collectively "plaintiffs") bring this diversity action against defendant Sulzer Orthopedics, Inc. ("defendant"), alleging various state law causes of action with respect to the implantation of a prosthetic knee replacement system inserted into Mr. Billone's right knee in 1996. Defendant now moves to preclude the testimony of plaintiffs' expert witness, and for summary judgment in its favor. For the reasons set forth below, defendant's motion to preclude the testimony of plaintiffs' expert witness is denied and its motion for summary judgment is: granted with respect to plaintiffs' strict liability for negligent manufacture claim, duty to warn claim and breach of express warranty claim; and denied with respect to plaintiffs' strict liability for negligent design claim, negligent design, manufacture and inspection claim and breach of implied warranty claim.

BACKGROUND

Mr. Billone has experienced pain in his right knee since he was a teenager, and in 1996 decided to undergo partial knee

replacement surgery on the advice of Dr. Stephen L. Kates. On April 22, 1996, Dr. Kates successfully implanted a "Natural Knee Unicompartmental Replacement System" (the "implant" or "knee replacement system") in Mr. Billone's right knee. The implant, which is designed and manufactured by defendant, is intended to be an alternative to total knee replacement for patients suffering unicompartmental knee disease. It is a symmetric system consisting of a cast cobalt-chromium femoral component, a wrought titanium alloy tibial base plate and an ultra high molecular weight polyethylene tibial insert.

After surgery, Dr. Kates warned plaintiff not to overuse the knee during recovery, since the implant is indicated for patients with a more sedentary lifestyle. However, shortly after the surgery, Mr. Billone returned to his busy plumbing and mechanical business, and undertook several home improvements. Mr. Billone met with Dr. Kates on several occasions subsequent to the surgery to review the implant's status. Each time, Dr. Kates warned plaintiff not to overuse his knees.

In September 1997, plaintiff complained to Dr. Kates about pain in his right knee. X-rays revealed that a fragment of the implant had broken from the posterior portion of the tibial base plate and had shifted within the knee. Remedial surgery was needed, and was completed in November 1997. Plaintiffs now bring suit, alleging, inter alia, that the implant was defective.

In support of their claims, plaintiffs have engaged the services of Dr. David J. Quesnel, a mechanical engineer and professor at the University of Rochester, who holds a Ph.D. in Materials Science and Engineering and an M.S. in Materials Science. Plaintiffs expect that Dr. Quesnel will testify that the implant failed as a result of a design and manufacturing defect found in the tibial base plate component and also as a result of a design defect and manufacturing defect in the tibial insert component.

DISCUSSION

I. Defendant's Motion to Preclude Plaintiff's Use of Quesnel's Expert Testimony

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed.R.Evid. 702.

In Daubert v. Merrell Dox Pharmaceuticals, Inc., the Supreme Court established the role of district courts as "gatekeepers," charged with the responsibility of ensuring that scientific expert testimony is both relevant and reliable. See 509 U.S. 579 (1993).

See also Kuhmo Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999) (applying Daubert gatekeeping role to evaluation of testimony by engineers concerning product manufacture or design).

"[T]he District Court must determine whether the proffered testimony has a sufficiently reliable foundation to permit it to be considered." Amorgianos v. National Railroad Passenger Corporation, 303 F.3d 256, 265 (2d Cir.2002) (quoting Daubert, 509 U.S. at 597). In Daubert, the Supreme Court listed several factors which district courts may look to in assessing the reliability of proposed expert testimony, including: (1) whether the expert's testimony is capable of being tested; (2) whether the theory proffered by the expert has been subjected to peer review; (3) the known or potential rate of error associated with the expert's underlying techniques; (4) whether standards or controls were used in testing; and (5) whether the technique and theory employed by the expert are generally accepted in the relevant scientific community. 509 U.S. at 592-594.

However, "the test of reliability is 'flexible,' and Daubert's list of specific factors neither necessarily nor exhaustively applies to all experts or in every case." Kumho Tire Company LTD. v. Carmichael, 526 U.S. 137, 141(1999). The Court's objective is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Id., at 151.

Defendant anticipates that Dr. Quesnel will testify that in his opinion, the implant removed from Mr. Billone failed as a result of defective design and inferior manufacturing. Defendant contends that Dr. Quesnel's opinion should be excluded from consideration at trial because he: (1) is not an expert in the use, manufacture or design of prosthetic devices; (2) failed to consider whether plaintiff was the type of patient the manufacturer intended or expected would receive the knee replacement system; (3) failed to consider condition of plaintiff's ACL prior to surgery in relation to the wear on the knee replacement system; (4) failed to consult industry standards regarding possible alternative grades of polyethylene suitable for use in prosthetic devices; and (5) failed to conduct tests on the knee replacement system itself to prove his theory of causation. As such, defendant argues, Dr. Quesnel is not qualified to render an expert opinion and his opinions are unreliable and should be excluded from consideration at trial.

Defendant is correct in stating that while "trained experts commonly extrapolate from existing data . . . nothing in either Daubert or the Federal Rules of Evidence require[s] a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997). In fact, courts should exclude expert testimony that is "speculative or conjectural, or if it is based on

assumptions that are so unreasonable and contradictory as to suggest bad faith. . . ." Boucher v. Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir.1996). However, where an expert's underlying methodology is reliable, defects in the conclusion drawn should be explored on cross-examination and go the weight of the evidence, not its admissibility. McCullock v. H.B. Fuller Company, 61 F.3d 1038, 1043 (2d Cir.1995). Moreover, the Supreme Court has emphasized the "liberal thrust" of Rule 702, favoring the admissibility of expert testimony. Blanchard v. Eli Lilly & Co., 207 F. Supp.2d 308, 316 (D.Vt.2002) (quoting, Daubert, 509 U.S. at 588).

I find that Dr. Quesnel's professional engineering experience and the methodology he used in rendering his opinion satisfies the requirements of Federal Rule of Evidence 702, and that defendant's criticisms of Dr. Quesnel's opinions may be explored on cross-examination rather than by defendant's motion to completely exclude such testimony. Dr. Quesnel's curriculum vitae and deposition testimony demonstrate that he is an expert in the field of product design. He has more than thirty years of mechanical engineering experience and currently serves as a consultant in "Failure Analysis & Investigative Engineering," where he investigates the causes of "automobile chassis failures, engine component failures and fracture of glassware." See Curriculum Vitae of Dr. David J. Quesnel, p. 36, Defendant's Appendix to Local Rule 56.1 Statement of Material Facts, Ex. O (Doc. No. 45). He also currently teaches

biomechanics at the University of Rochester, where he evaluates the joints, structures and components of the human body in relation to the loads forces and stresses they must endure. See Deposition of Dr. David J. Quesnel, pp. 34-36, Defendant's Appendix to Local Rule 56.1 Statement of Material Facts, Ex. P (Doc. No. 45). In addition, Dr. Quesnel apparently will rely upon his personal examination of the knee replacement system that was removed from Mr. Billone. As such, there exists a sufficiently reliable basis for Dr. Quesnel to offer his expert opinion as to why the knee replacement system removed from Mr. Billone was defective. Defendant may, upon cross-examination, contest Dr. Quesnel's conclusions, however, the ultimate value of Dr. Quesnel's testimony will be left to the determination of the fact finder.

II. Defendant's Motion for Summary Judgment

Rule 56 of the Federal Rules of Civil Procedure provides that a party is entitled to summary judgment as a matter of law only where, "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact. . . ." FED.R.CIV.P. 56(c). The party seeking summary judgment bears the burden of demonstrating that no genuine issue of material fact exists, and in making the decision the court must draw all reasonable inferences in favor of the party against whom summary judgment is sought. Ford v. Reynolds, 316 F.3d 351, 354 (2d

Cir.2003) (citing Marvel Characters v. Simon, 310 F.3d 280, 285-86(2d Cir.2002)). "Summary judgment is improper if there is any evidence in the record that could reasonably support a jury's verdict for the non-moving party." Id.

A. Plaintiffs' Strict Liability Claim

In an action for strict products liability, a plaintiff may assert that the product is defective due to a mistake in manufacturing, improper design or a manufacturer's failure to provide proper warning regarding the use of the product. Fane v. Zimmer, 927 F.2d 124 (2d Cir.1991). To state a valid claim under any of these strict products liability theories, a plaintiff must demonstrate that: (1) the product is "defective" because it is not reasonably safe as marketed; (2) the product was used for its normal purpose; (3) the defect was a substantial factor in causing the plaintiff's injuries; (4) the plaintiff, having exercised reasonable care, would not have been able to discover the defect; and (5) the plaintiff would not have otherwise avoided the injury through the use of ordinary care. Urena v. Biro Manufacturing Company, 114 F.3d 359, 363 (2d Cir.1997).

Plaintiff first claims that defendant is strictly liable for an allegedly defective design of the knee replacement device. Under New York State Law, a device is of defective design were it is "not reasonably safe or presented an unreasonable risk of harm to the user." Fane 927 F.2d at 128. Thus, a plaintiff must

demonstrate that the product "presented a substantial likelihood of harm and feasibly could have been designed more safely." Id.

Here, plaintiffs present sufficient proof to survive summary judgment as to whether the knee replacement system removed from Mr. Billone was defectively designed. First, Dr. Quesnel's expected expert testimony that the implant was improperly designed creates an issue of fact for determination by the fact finder. As defendant explained in its motion to preclude Dr. Quesnel's testimony, there are numerous questions concerning the soundness of that opinion. Second, it can be inferred from Dr. Quesnel's expert report that the knee replacement system may have been safer if the polyethylene used within the device was of a stronger grade. See Report of Dr. David J. Quesnel, p. 2, Defendant's Appendix to Local Rule 56.1 Statement of Material Facts, Ex. M (Doc. No. 45). Furthermore, defendant's arguments that the knee implant device had been inspected numerous times and that "only one other implant had ever been reported to Sulzer as breaking" are unpersuasive in the context of this motion for summary judgment. See Defendant's Reply Memorandum of Law in Support of Its Motion to Preclude Plaintiffs' Expert Testimony and for Summary Judgment, p. 1 (Doc. No. 49-1). While certainly compelling evidence, it is precisely the type of evidence, together with other relevant evidence that should be presented to a jury.

Plaintiffs also assert a cause of action for defective manufacture of the knee replacement system removed from Mr. Billone. In a manufacturing defect case, the plaintiff must prove

that "the product failed to perform in the intended manner due to a flaw in the manufacturing process." Macaluso v. Miller, 2005 WL 563169 at *5 (S.D.N.Y.2005) (citing Denny v. Ford Motor Company, 662 N.E.2d 730, 735, n.3 (N.Y.1995)).

Plaintiffs have apparently abandoned this claim, since they did not present any questions of fact with regard to whether the knee replacement system was defectively manufactured, nor did they assert any argument in their Opposition to Defendant's Motion for Summary Judgment. See Plaintiffs' Memorandum of Law (Doc. No. 48). Accordingly, judgment is granted in favor of defendant on plaintiffs' strict liability defective manufacturing claim, and that claim is dismissed with prejudice.

B. Plaintiffs' Negligent Design, Manufacture and Inspection Claim

Plaintiffs also argue that defendant is liable for the injuries plaintiff suffered as a result of the failure of the knee implant because it was negligent in the design, manufacture and inspection of the implant. To prove negligence under New York State Law, a plaintiff must demonstrate that: (1) defendant had a duty to plaintiff; (2) defendant breached that duty; and (3) the breach of duty was the proximate cause of the plaintiff's injuries. Fernandez v. Chios Shipping Co., Ltd., 542 F.2d 145, 155 (2d Cir.1976).

Defendant asserts that it is entitled to summary judgment in its favor on plaintiffs' negligence claim because plaintiffs are unable to establish the second and third elements necessary to

state a valid claim of negligence. I find otherwise. As explained above, Dr. Quesnel's anticipated expert testimony that a design defect caused the failure of the implant, and thereby injured Mr. Billone, creates sufficient questions of fact so as to allow plaintiffs' negligence claim to proceed to determination by a fact finder. If defendant in fact improperly designed, manufactured or inspected the implant, as opined by Dr. Quesnel, and that defect caused the failure of the implant, also as opined by Dr. Quisnel, then defendant may have been negligent. Defendant's evidence to the contrary, including the implant contraindications and limitations for its use, is an insufficient basis for the Court to declare as a matter of law that defendant was not negligent in the design, manufacture and inspection of the implant. Accordingly, defendant's motion for summary judgment on plaintiffs' negligence claim is denied.

C. Plaintiffs' Duty to Warn Claim

Plaintiffs next allege that defendant was negligent in failing to properly warn users that the implant might fail. To state a valid cause of action for failure to properly warn, a plaintiff must demonstrate that "the warning was inadequate and that the failure to adequately warn of the dangers of the [implant] was a proximate cause of his or her injuries." Krasnopolsky v. Warner-Lambert Company, 799 F. Supp. 1342, 1346 (E.D.N.Y.1992). However, under the informed intermediary doctrine, a manufacturer of a medical device has no duty to warn the patient directly, but instead must properly warn the physician who has a duty to act as

an "informed intermediary" between the manufacturer and the patient. Prohaska v. Sofamor, S.N.C., 138 F. Supp.2d 322, 344 (W.D.N.Y.2001). "If the doctor is sufficiently warned, the product is not defective.... Nor is a manufacturer responsible for how a learned intermediary conducts his business." Id.

In support of its motion for summary judgment on this claim, defendant proffers the deposition testimony of Mr. Billone's physician, Dr. Kane, which states that he was adequately informed of the implant's limitations, specifically that: (1) the package insert included with the product adequately explained the risks associated with the implant, including those of which plaintiff presently complains; (2) he was aware of the limitations of the implant; and (3) he communicated this information to Mr. Billone prior to inserting the implant in 1996. See Deposition Transcript of Dr. Stephen L. Kates, pp. 16-17, Defendant's Appendix to Local Rule 56.1 Statement of Material Facts, Ex. J (Doc. No. 45).

In their opposition to defendant's motion for summary judgment, plaintiffs claim that defendant carries the burden of proof with respect to proving the sufficiency of the warning. Nonetheless, plaintiffs neither disagree with the informed intermediary doctrine, nor offer proof to rebut the substance of Dr. Kates' deposition testimony. After a thorough review of the evidence, I conclude as a matter of law that defendant adequately warned Dr. Kates of the risks associated with the implant. Since defendant provided sufficient warning to Dr. Kates, plaintiffs' failure to properly warn claim is dismissed with prejudice.

D. Plaintiffs' Breach of Warranty Claims

Lastly, plaintiffs assert that defendant is liable for breach of express warranty as well as breach of implied warranty because the implant was defective, unmerchantable, unsafe and otherwise unfit for its intended purpose.

For a plaintiff to prevail on a breach of express warranty claim, defendant must make an express warranty. Daley v. McNeil Consumer Products Co., 164 F.Supp. 2d 367, 376 (S.D.N.Y.2001). Plaintiffs have failed to present evidence of any such express warranty made by defendant. Accordingly, defendant's motion for summary judgment in its favor on plaintiffs' breach of express warranty claim is granted, and that claim is dismissed with prejudice.

For a plaintiff to prevail on a cause of action alleging breach of implied warranty, he must prove that:(1) the product was defectively designed or manufactured; (2) the defect existed when the manufacturer delivered it to the purchaser or user; and (3) the defect is the proximate cause of plaintiff's injuries. Silivanch v. Celebrity Cruises, Inc., 171 F.Supp.2d 241, 259 (S.D.N.Y.2001). "One who sells a product in a defective condition unreasonably dangerous at the time it is sold[,] to the consumer or his property[,] is subject to liability for physical harm. A product may be defective if the seller fails to give reasonable warnings of danger or a defect in the product known at the time of manufacture or discovered afterwards when the seller by exercising reasonable

diligence, could have made such warnings or instructions available to the user or consumer."

Here, defendant contends that it is entitled to summary judgment on plaintiffs' breach of implied warranty claim because Dr. Quesnel's opinion is "speculative at best", that Dr. Quesnel fails to propose a safer alternative and that the implant was not defective when inserted into Mr. Billone by Dr. Kates in 1996. In support of this assertion defendant cites statistics which indicate that no other implant from the same lot as Mr. Billone's malfunctioned and that since 1989 only one complaint similar to plaintiffs' has been reported. However, as discussed above, when viewed along with Dr. Quesnel's expert opinion, these arguments create material facts best left for the determination of a jury. Furthermore, plaintiff need not prove that there exists a safer alternative to the implant in order to state a valid claim of breach of implied warranty, since that is not an element necessary to establish a prima facie case under that cause of action. Groome v. Matsushita Electric Corp., 2000 WL 341134 (E.D.N.Y.2000). Accordingly, plaintiffs have presented sufficient questions of material fact with respect to their breach of implied warranty claim, and defendant's motion for summary judgment on that claim is denied.

CONCLUSION

For the reasons set forth above, I find that Dr. Quesnel's expert opinion meets the requirements of Rule 702 of the Federal Rules of Evidence, and thus is admissible. I also find that

plaintiffs have presented sufficient questions of material fact to survive defendant's motion for summary judgment with respect to their strict liability for negligent design claim, negligent design, manufacture and inspection claim and breach of implied warranty claim. However, no questions of material fact exist with respect to plaintiffs' strict liability for negligent manufacture claim, duty to warn claim and breach of express warranty claim. Accordingly, defendant's motion to exclude the expert testimony of Quesnel is denied. Defendant's motion for summary judgment is granted with respect to plaintiffs' strict liability for negligent manufacture claim, duty to warn claim and breach of express warranty claim and those claims are dismissed with prejudice; and denied with respect to plaintiffs' strict liability for negligent design claim, negligent design, manufacture and inspection claim and breach of implied warranty claim.

ALL OF THE ABOVE IS SO ORDERED.

S/ Michael A. Telesca

MICHAEL A. TELESCA
United States District Judge

Dated: Rochester, New York
August 25, 2005